

WHAT IS CLAIMED IS:

- 5 1. A stable suspension of a biologically active protein suited for aerosol delivery to the respiratory tract of a patient in need of treatment comprising particles of said protein suspended in ethanol.
2. A stable suspension according to claim 1 wherein said ethanol is
10 substantially anhydrous.
3. A stable suspension according to claim 1 wherein said ethanol contains less than 5% water.
- 15 4. A stable suspension according to claim 1 wherein said ethanol contains less than 3% water.
5. A stable suspension according to claim 1 wherein said biologically active protein is selected from the group comprising enzymes, antibodies,
20 antigens, hormones and cytokines.
6. A stable suspension according to claim 5 wherein said therapeutically active protein is a hormone.
- 25 7. A stable suspension according to claim 6 wherein said therapeutically active protein is insulin.
8. A stable suspension according to claim 5 wherein said therapeutically active protein is a cytokine.
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9. A stable suspension according to claim 5 wherein said therapeutically active protein is Factor VIII.

10. A stable suspension according to claim 1 wherein the particle size of said protein is from about 0.01 μ to about 10.0 μ .

5 11. A stable suspension according to claim 10 wherein the particle size of said protein is from about 5.0 μ to about 10.0 μ .

12. A stable suspension according to claim 11 wherein the particle size of said protein is from about 0.01 μ to about 3.0 μ .

10 13. A stable suspension according to claim 1 wherein said suspension contains up to 20% V/V of a formulation additive.

14. A stable suspension according to claim 13 wherein said suspension formulation additive is selected from the group consisting of
15 glycerol, propylene glycol and polyethylene glycol.

15. A stable suspension according to claim 1 wherein said suspension contains from about 0.5% to about 5.0% of a pharmaceutically acceptable excipient.

20 16. A stable suspension of insulin useful for aerosol delivery to the lungs of a patient in need of treatment comprising particles of a pharmaceutically effective amount of insulin suspended in ethanol.

25 17. A stable suspension according to claim 16 wherein said insulin is present in the suspension at a concentration of from about 1.0 mg/ml to about 200.0 mg/ml of suspension.

30 18. A stable suspension according to claim 16 wherein the particle size of said insulin is from about 0.01 μ to about 5.0 μ .

19. A stable suspension according to claim 16 wherein said suspension contains up to 20% V/V of a formulation additive.

20. A stable suspension according to claim 19 wherein said suspension formulation additive is selected from the group consisting of glycerol, propylene glycol and polyethylene glycol.

5 21. A stable suspension according to claim 16 wherein said suspension contains from about 0.5% to about 5.0% of a pharmaceutically acceptable excipient.

10 22. A method of delivering a therapeutically effective amount of a protein to the respiratory tract of a patient in need of treatment which comprises producing an aerosol of a stable liquid suspension of said protein using an electrostatic spraying means wherein said liquid suspension comprises particles of said protein suspended in ethanol.

15 23. A method according to claim 22 wherein said protein is selected from the group comprising enzymes, antibodies, antigens, hormones and cytokines.

20 24. A method according to claim 23 wherein said therapeutically active protein is a hormone.

25 25. A method according to claim 24 wherein said hormone is insulin.

26 26. A method according to claim 23 wherein said protein is a cytokine.

27 27. A method according to claim 26 wherein said cytokine is Factor VIII.

30 28. A method according to claim 22 wherein the particle size of said protein is from about 0.01 μ to about 10.0 μ .

29. A method according to claim 28 wherein the particle size of said protein is from about 5.0 μ to about 10.0 μ .

30. A method according to claim 29 wherein the particle size of said protein is from about 0.01 μ to about 3.0 μ .

31. A stable suspension according to claim 22 wherein said
5 suspension contains up to 20% V/V of a formulation additive.

32. A stable suspension according to claim 31 wherein said
suspension formulation additive is selected from the group consisting of
glycerol, propylene glycol and polyethylene glycol.
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33. A stable suspension according to claim 22 wherein said
suspension contains from about 0.5% to about 5.0% of a pharmaceutically
acceptable excipient.
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